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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,380	02/08/2002	Li-Lan H. Chen	366325-503	1761
25561 7	7590 03/19/2003			
ALLEN BLOOM			EXAMINER	
C/O DECHERT PRINCETON PIKE CORPORATION CENTER			BENNETT, RACHEL M	
P.O. BOX 521		ENTER		
PRINCETON, NJ 08543-5218			ART UNIT	PAPER NUMBER
		•	1615	10
			DATE MAILED: 03/19/2003	4
				/

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
,	10/071,380	CHEN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Rachel M. Bennett	1615				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status	36(a). In no event, however, may a reply be tin within the statutory minimum of thirty (30) day vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).				
1) Responsive to communication(s) filed on 29 h	<u>flay 2002</u> .					
2a) This action is <b>FINAL</b> . 2b) Thi	is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) <u>1-44</u> is/are pending in the application						
	4a) Of the above claim(s) is/are withdrawn from consideration.					
	5) Claim(s) is/are allowed.					
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8)⊠ Claim(s) <u>1-44</u> are subject to restriction and/or election requirement.  Application Papers						
9) The specification is objected to by the Examiner						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents	1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents	2. Certified copies of the priority documents have been received in Application No					
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language pro- 15)☐ Acknowledgment is made of a claim for domesti	visional application has been rec	eived.				
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal I	/ (PTO-413) Paper No(s) Patent Application (PTO-152)				
O. Dekember of Traditional Office		<del></del>				

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## **DETAILED ACTION**

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-16, drawn to composition, classified in class 424, subclass 489.
- II. Claims 17-44, drawn to methods, classified in class 424, subclass 464.The inventions are distinct, each from the other because of the following reasons:
- 2. Inventions of Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process can make other and materially different products. Applicants themselves claim a method of making a composition, a method of making a complex, and a method for enhancing the water solubility of an active agent.
- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- 4. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

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5. This application contains claims directed to the following patentably distinct species of the claimed invention: If Applicants elect the composition of Group I, Applicants are further required to elect from Species I: an active agent AND from Species II: a dosage form

Species in Group I:

- a) elect one of the active agents disclosed in claims 5-9, and 13 Species in Group II:
- b) elect one of the dosage forms disclosed in claim 15

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600